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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,507	03/01/2004	Albert Pierce	VPI/03-12 US	1051
27916 7590 07/22/2009 VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242				
EXAMINER ZHOU, SHUBO				
ART UNIT 1631		PAPER NUMBER		
MAIL DATE 07/22/2009		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/790,507

**Applicant(s)**

PIERCE ET AL.

**Examiner**

SHUBO (Joe) ZHOU

**Art Unit**

1631

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 42-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendments/Response***

Applicants' amendments and request for reconsideration in the response filed 4/23/09 are acknowledged and the amendments have been entered.

### ***Status of the Claims***

Claims 1-39 and 42-46 are currently pending and under examination.

Claims 40-41 had been previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim, and have been canceled in the amendment filed 4/23/09.

### ***Specification***

The objection to the specification set forth in the previous Office action is withdrawn in view of applicant's amendment filed 4/23/09, where a new Abstract is filed.

### ***Claim Rejections-35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-39 and 42-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated from the previous Office action mailed 11/3/08.

Applicant's arguments filed 4/23/09 have been fully considered but they are not persuasive. Applicant argues that the Office action is not in line with current law as promulgated by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008). Applicant seems to rely on the court's explanation of *Abele*, which applicant states, involves claims reciting a process of graphically displaying variances of data from average values, in *In re Bilski* to argue that electronic data transformation also constitutes physical transformation. Applicant seems to argue that since the sources of the data are by X-ray, NMR, etc, the claims should be patent-eligible. This is not found persuasive. While the court in *In re Bilski* considers the importance of the nature of the data analyzed, it also points out the importance of what the data represents and what the claimed process produces/transforms. In the case of *Abele*, where a dependent claim is held patent eligible, the court in *In re Bilski* states that the "data clearly represented physical and tangible objects, namely the structure of bones, organs and other body tissues. Thus the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible." See *In re Bilski*, 88 USPQ2d 1397. In the instance case, however, even though the data source may be from X-ray, NMR, etc., the raw data were not transformed into a particular visual depiction of a physical object on a display to render the claims patent eligible. Therefore, at least one embodiment of the claimed invention is nonstatutory.

***Claim Rejections-35 USC § 112***

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39, 42-43, and 45-46 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in step (1) recites “a set of models, wherein each model comprises three-dimensional structural information ... wherein each model is related to the other models of the set by a homologous structural feature.” The term "homologous" is a relative term that renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. When the 3-D structures of two molecules are compared, some part of the molecules might share the same atoms at corresponding positions, and some different atoms might share the same spatial shape or form. Without an explicit standard or criteria for determining whether two structures are homologous, it would not be clear to one skilled in the art what structures are homologous and what are not.

The metes and bounds of the claimed inventions in other claims reciting homologous structural feature, such as claim 39, are unclear, and the claims are thus rejected for the same reasons set forth above.

This rejection is reiterated from the previous Office actions. Applicant in the response filed 4/23/09 again argues that the specification throughout provides guidance and examples of homologous features used in the invention. However, a review of the specification reveals that it only gives certain examples. It's the examiner's position that

Art Unit: 1631

absent a clear standard or criteria for determining homology for structural features, which could be any structural features including peptide, nucleic acid, sugar, lipid, etc., one of ordinary skill in the art would not be apprised of the scope of the invention. Even for those examples given, it would be unclear whether those falling outside the range of the examples would be considered as homologous without a clear standard to ascertain. Applicant states that the specifications asserts that when the target molecule is a protein, homologous is standardized in terms of amino acid homology, and amino acid homology may be 25%, 40%, or greater. However, the specification does not define the exact scope of homology. For instance, one of ordinary skill in the art would not know whether a 20% identity would be considered as homologous. Furthermore, if the target molecule is a molecule other than a peptide, a nucleic acid, one would not know how to determine whether two structural features are homologous.

Clarification of the metes and bounds of the claims is requested.

### ***Conclusion***

No claim is allowed.

### **THIS ACTION IS MADE FINAL.**

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the

Art Unit: 1631

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER